

## REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Currently, claim 1 is amended, claim 2 is canceled, and claim 3 is added. After revising the claims as set forth above, claim 1 and 3 will be pending.

### Amendments to the Specification

Applicants amend the specification to correct any identified errors and to properly reference any trademarks. Additionally, applicants amend the specification to relocate the section, entitled “A Brief Description of the Drawings,” to follow the Brief Summary of the Invention as discussed in paragraph 7 of the office action.

### Information Disclosure Statement

The examiner objected to the citations of references within the application without a separate Information Disclosure Statement. Applicants note that the examiner has considered the Information Disclosure Statements filed on February 9, 2004, which, to applicants’ knowledge, lists all of the references cited in the application. Applicants therefore request withdrawal of this objection.

### Rejection under 35 USC 112

The examiner rejected claims 1 and 2 as indefinite, based on her concern over the phrase “an antigenic preparation.” Additionally, the examiner rejected claim 2 for alleged lack of “written description” support.

Without acquiescing to the examiner’s contentions, applicants have canceled claim 2 in order to advance prosecution. Applicants likewise have revised claim 1 to remove the “an antigenic preparation.” Thus, claim 1 now prescribes “an antigen comprising the CB10 peptide of mammalian type II collagen or an antibody binding fragment of said peptide....” In light of these changes, applicants request reconsideration and withdrawal of the rejections in question.

**Rejection under 35 USC 103**

Claims 1 and 2 stand rejected over Boisser *et al.* (1991) and, Cremer *et al.* (1992), respectively, in view of Foster *et al.* (1984). Yet the cited prior art neither teaches such a kit nor evidence the motivation or a suggestion to create such a kit.

Claim 1 relates to a kit for detecting the development of rheumatoid arthritis, comprising “an antigen comprising the CB10 peptide of mammalian type II collagen or an antibody-binding fragment of said peptide and (ii) means for detecting a complex formed between said antigen and antibody from said sample.” As the PTO recognized in the parent case, the prior art does not suggest the measurement of the CB10 peptide of mammalian type II collagen as an indicator of rheumatoid arthritis.

While the primary references considered the use of anti-CB10 antibody, in the context of assessing susceptibility to rheumatoid arthritis, both Boisser and Cremer concluded that the tested antibody was not useful to this end. It is beyond dispute, therefore, that neither reference would have motivated one of ordinary skill to create a kit as presently claimed. In other words, there was no identified use for the kit components and, hence, no desire or need to have put them together in kit fashion, per the teachings of Foster. This lack of motivation in the art is reflected in the 5-year period between the first associated with the present invention and the latest publication date of any cite reference.

For these reasons alone, the examiner has not made out a *prima facie* case under Section 103. Accordingly, applicants submit that the pending claims are allowable over the cited combination and that this rejection should be withdrawn.

Dependant claim 3 is separately patentable, moreover, for its recitation of a written set of instructions to implement a methodology for using the other kit components in a manner not presaged by the art of record. *Cf. In re Ngai*, 367 F.3d 1336 (Fed. Cir. 2004) (supporting the patentability of a kit comprising various components, including instructions when no such kit exists in the prior art).

## CONCLUSION

Applicants believe that the present application is now in condition for allowance.  
Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By



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